

REMARKS/ARGUMENTS

Claims 1-95 were pending. Claims 1-23, 25, 34, 35, 37-41, 45, 48, 49, 87-89 and 93 were examined and rejected. The remaining claims were withdrawn pursuant to a prior election of species, except for claims 91 and 92 which were withdrawn in response to a restriction requirement. Claims 91-95 are canceled without prejudice to refiling in a subsequent application. Applicants believe that all remaining claims should now be examined in view of the amendment to claim 1 which it is believed places that claim in condition for allowance.

Applicants note the objection to the drawings and have provided corrected drawings for approval by the Examiner. Paragraph [0064] has been corrected as suggested by the Examiner

Applicants note the objection to the specification and have corrected the spelling of "hyaluronate" in paragraph 13 of the specification.

Claims 16 and 39 were objected to. Both claims have been amended as suggested by the Examiner.

Claim 89 was rejected for indefiniteness. Claim 89 has been amended to change the dependency to claim 88 rather than claim 87.

Claims 93-95 have been canceled, thus rendering the rejection of claim 93 as being directed to non-statutory subject matter moot.

All examined claims were rejected as being anticipated by U.S. Patent No. 6,095,968 to Snyders. Applicants have amended claim 1 to overcome this rejection. It is believed that this amendment clearly distinguishes Snyders, even when combined with the teachings of U.S. Patent No. 6,241,654 to Alferness, U.S. Patent No. 5,897,587 to Martikos et al., and/or U.S. Patent No. 5,131,907 to Williams et al.

Snyders '968 describes a cardiac pump device that can be modified *in situ* to become a cardiac reinforcement device. To fulfill this role, the device comprises an inelastic outer layer which, when positioned, may be sutured to the pericardium. The device further consists of an elastic inner layer which, when positioned, engages the epicardium. Once in place, fluid may be pumped in and out of the region between the outer and inner surfaces in order to compress the ventricles of the heart through assisted pumping. The device requires both

the inelastic outer layer and the elastic inner layer in order to achieve its initial purpose as a pump. In order convert the device to a passover straight, a silicone material is introduced into the space and left there chronically, i.e. it is not thereafter pumped.

The device of the present invention, in contrast, is not intended to form an inner volume which is capable of receiving a pumped fluid in order to compress the heart. Instead, it is intended to be either an integrated or laminated structure having an inner lubricious surface for contacting the heart and an outer surface for adherence to the pericardium, typically by tissue ingrowth or other natural processes. There is no intention for inner and outer layers to be separated from each other, and the device of the present invention instead acts as a pericardial reinforcement in order to restrain heart enlargement.

For the reasons just described, Applicants believe that claim 1 clearly distinguishes the structure taught in Snyders. That is, claim 1 sets forth "A compliant and substantially non-elastic pericardial reinforcement" The Snyders device, in contrast, must be elastic on its inner surface in order to fulfill the pumping function described. In an effort to further distinguish Snyders, however, Applicants have amended independent claim 1 to further recite that the non-elastic pericardial reinforcement comprises "an enclosure generally conforming in shape to at least a portion of the heart, said enclosure consisting essentially of" a compliant and substantially non-elastic member having an interior surface for placement adjacent an epicardium. . . ." By this amendment, Applicants specifically intend to exclude two-component enclosure systems such as described by Snyders where an elastic membrane forms an envelope with an outer non-elastic component in order to provide the pump structure which can later be filled with silicone or other material in order to define the constraint.

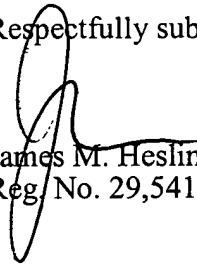
For these reasons, Applicants believe that claim 1, as well as all claims depending thereon, clearly distinguish over Snyders et al. Moreover, as none of the cited secondary art teaches such integrated or laminated structures for constraining the heart, Applicants believe that all claims are clearly in condition for allowance and request that the application be passed to issue at an early date.

Appl. No. 09/963,848
Amdt. dated November 17, 2003
Reply to Office Action of July 18, 2003

PATENT

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (650) 326-2400.

Respectfully submitted,


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Attachments: *2 sheets Replacement Drawings*
2 sheets Annotated Drawings

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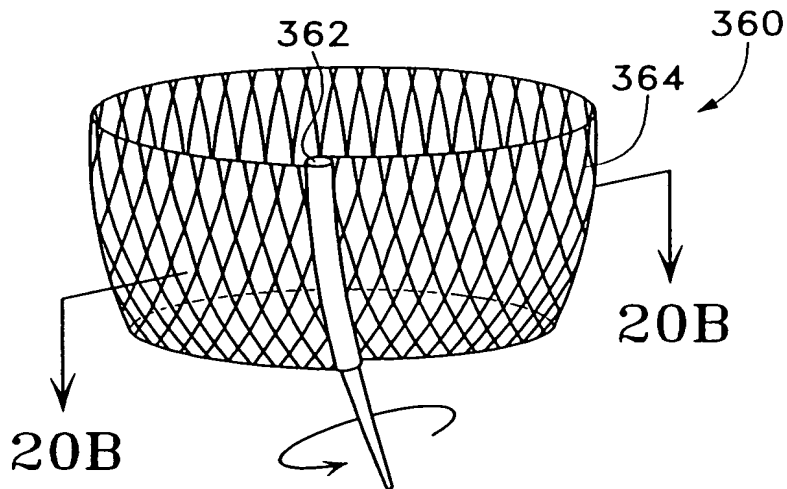


Fig. 20A

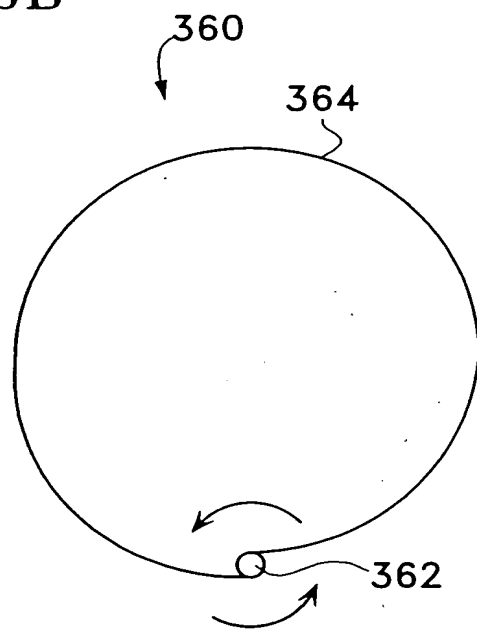


Fig. 20B

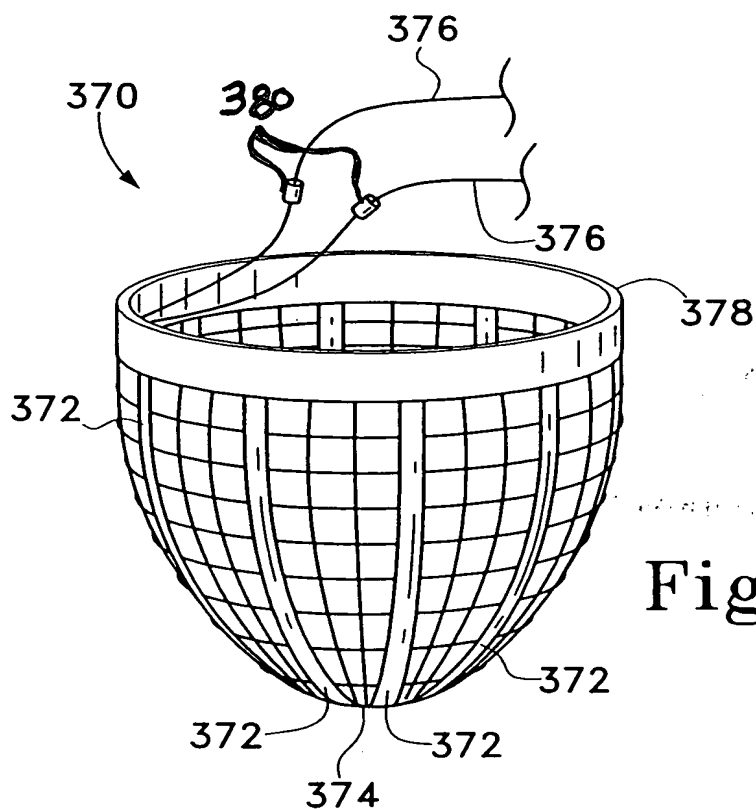


Fig. 21

Approved
2/28/04